

December 14, 1993

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OFFICE OF POLLUTION
PREVENTION AND TOXICS

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8EHQ-1293-12787

Contains No CB!

Office of Pollution Prevention and Toxics
U. S. Environmental Protection Agency

401 M Street, SW Washington, DC 20460 ATTN: 8(e) Coordinator

0540-93-12797

93-12787 12/16/93

88949999972

Dear Sir or Madam:

Subject:

Report submitted in accordance with U. S. Environmental Protection Agency Statement of Interpretation and Enforcement policy; Notification of Substantial

Risk-Section 8(e) TSCA.

The following information is submitted in accordance with the above statement. The submission pertains to two structurally similar chemicals: poly[oxy(methyl-1,2-ethanediyl)], α-hydro-ω-hydroxy-, ether with bis[[2-hydroxyethyl)amino]methyl]phenol (3:1) (product name THANOL® R-350X Polyol) [CAS # 068909-26-2] and formaldehyde, polymer with nonylphenol, reaction products with diethanolamine and propylene oxide (product name THANOL® R-650X Polyol) [CAS# 068610-97-9].

We do not believe that the information in the enclosed two reports reasonably supports the conclusion that the substances present a substantial risk. It is, however, being submitted to enable the Agency to draw its own conclusions.

In an eye irritation screening study in rabbits, both chemicals caused moderate to strong eye irritation in the unwashed eyes. Immediate irrigation of the eyes was palliative.

THANOL® R-350X Polyol and THANOL® R-650X Polyol are reacted with diisocyanates to produce rigid foams for use in construction and insulation. Unreacted THANOL® is not expected to be present in the final product. We are not aware of any adverse health problems associated with the use of either THANOL® Polyol. Copies of the Material Safety Data Sheets for both THANOL® Polyols are enclosed with this submission.

Please contact me if additional information is required.

Sincerely,

R. Hays Bell (716) 722-5036

RHB:JAF

Enc.

R. Hays Bell, Ph.D., Vice-President and Director, Corporate Health, Safety, and Environment Eastman Kodak Company, Rochester, NY 14652-3615

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STUDY TITLE

THANOL R-350X POLYOL (PM 17276)

ACUTE EYE IRRITATION SCREENING STUDY IN THE RABBIT

HAEL NUMBER: 93-0099 KAN: 971130 CAS REGISTRY NUMBER: 068909-26-2

FINAL REPORT

<u>AUTHOR</u>

Kenneth P. Shepard, B.S.

PERFORMING LABORATORY

Toxicological Sciences Laboratory
Corporate Health and Environment Laboratories
Eastman Kodak Company
1100 Ridgeway Avenue
B-320 Kodak Park
Rochester, New York 14652-3615
USA

LABORATORY PROJECT ID

HAEL Number: 93-0099

STUDY SPONSOR

Eastman Chemical Company Kingsport, Tennessee 37622

STUDY COMPLETION DATE

November 23, 1993

QUALITY ASSURANCE INSPECTION STATEMENT

[21 CFR 58.35(B)(7), 40 CFR 792.35(B)(7), and 40 CFR 160.35(B)(7)]

STUDY: 93-0099-1 STUDY DIRECTOR: SHEPARD, K.P.

PAGE

ACCESSION NUMBER: 971130

11/16/93

STUDY TYPE:

RABBIT EYE IRRITATION

(AUDITOR, QUALITY ASSURANCE UNIT)

TO THE BEST OF MY KNOWLEDGE, THIS FINAL REPORT ACCURATELY DESCRIBES THE METHODS AND STANDARD OPERATING PROCEDURES, AND THE REPORTED RESULTS ACCURATELY REFLECT THE RAW DATA. THIS STUDY WAS INSPECTED BY 1 OR MORE PERSONS OF THE QUALITY ASSURANCE UNIT OF HAEL, EASTMAN KODAK COMPANY ROCHESTER, N.Y. AND WRITTEN STATUS REPORTS WERE SUBMITTED ON THE FOLLOWING DATES:

INSPECTION	PHASE(S)	STATUS REPORT
DATES	INSPECTED	DATES
10/18/93	PROTOCOL APPENDIX SUBMISSION	
	INITIALLY 2 RABBITS	
10/21/93	TEST ARTICLE DISTRIBUTION RECORDS	11/16/93
11/16/93	FINAL REPORT REVIEW	11/16/93

COMPLIANCE WITH GOOD LABORATORY PRACTICE STANDARDS

To the best of the signer's knowledge and belief, the study described by this report was conducted in compliance with the following Good Laboratory Practice Standards:

Annex 2 of the Organization for Economic Cooperation and Development Guidelines for Testing of Chemicals C(81)30 (Final) as required by Council Directive 87/18/EEC of December 18, 1986.

Kenneth P. Shepard, B.S.

Study Director

November 3, 1993

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ABSTRACT

THANOL R-350X POLYOL (PM 17276)

ACUTE EYE IRRITATION SCREENING STUDY IN THE RABBIT

HAEL NUMBER: 93-0099 KAN: 971130 CAS REGISTRY NUMBER: 068909-26-2

This screening study for eye irritation was initiated in lieu of a study using a complete set of animals because *in vitro* assays indicated that the test material might be an eye irritant even though prior experience with other test materials belonging to the same chemical class indicated that the test material would not be an irritant. A single dose of 0.1 milliliter of the test material was administered into the conjunctival sac of one eye of each of the two animals. One of the two treated eyes was washed with distilled water. The remaining treated eye was not irrigated.

Signs of irritation in the unwashed eye included strong erythema and strong edema of the conjunctiva and nictitating membrane and moderate erythema and moderate edema of the lids. A moderate discharge was also noted from the unwashed eye. When fluorescein dye was applied to the unwashed eye, staining of the conjunctiva and nictitating membrane was evident. Immediate irrigation of the eye was palliative. Signs of irritation noted in the washed eye included moderate erythema of the conjunctiva, moderate erythema and slight edema of the nictitating membrane, and slight erythema of the lids. A slight discharge was also noted from the washed eye one hour after dosing. Staining of the nictitating membrane was evident when the washed eye was tested with fluorescein dye.

Based on the responses observed, the material was classified as irritating to eyes, as defined in the 12th Adaptation on the EC Classification, Packaging, and Labelling of Dangerous Substances.

PERFORMING LABORATORY

Toxicological Sciences Laboratory
Corporate Health and Environment Laboratories
Eastman Kodak Company
1100 Ridgeway Avenue
B-320 Kodak Park
Rochester, New York 14652-3615
USA

SPONSOR

Eastman Chemical Company Kingsport, Tennessee 37622 Sponsor's Representative: W. Mills Dyer, Jr., M.D.

STUDY DATES

Study Initiation: October 18, 1993 Experiment Initiation: October 18, 1993 Experiment Completion: October 19, 1993

Study Completion: November 23, 1993

STUDY DIRECTOR

Kenneth P. Shepard, B.S.

OTHER KEY PERSONNEL

Len Sakal, B.S., Study Technician
John W. Mosher, B.S., Principal Investigator
Milan S. Vlaovic, D.V.M., Ph.D., Laboratory Animal Medicine

PURPOSE/OBJECTIVE

The purpose of this study was to determine the potential of the test compound to cause primary ocular irritation.

TEST SUBSTANCE

Test Material Name: THANOL R-350X Polyol

PM: 17276

CAS Registry Number: 068909-26-2 HAEL Laboratory Number: 93-0099

KAN: 971130 CIN: Not available

SRID or Lot I.D. Number: X22872-026A

Physical State and Appearance: Yellow viscous liquid Received at Performing Laboratory: August 9, 1993

Composition: Refer to composition information included in the notification when applicable.

TEST SYSTEM

Species: Rabbit

Strain: Hra:(NZW)SPF

Source: Hazleton Research Animals, Denver, PA, USA

No. of Animals: 2; 1 Washed/1 Unwashed

Sex: Not Determined

Body Weight Range at Dosing: Not Determined Age: Young Adults (At least three months old)

HUSBANDRY AND ENVIRONMENTAL CONDITIONS

Housing

All animals were individually housed in suspended, stainless-steel, mesh cages.

HUSBANDRY AND ENVIRONMENTAL CONDITIONS, Cont.

Environmental Conditions

A photoperiod of 12 hours light from 6 a.m. to 6 p.m.was maintained. Room temperature was maintained at 65-67°F. Relative humidity was maintained at 63-64%.

Diet and Water

Agway® Prolab™ High Fiber Rabbit Diet certified pellets and water (Monroe County (NY) Water Authority) were available ad libitum. No known contaminants which would interfere with the outcome of the study were expected to be present in feed or water from these sources. Analyses of feed and quarterly analyses of water are maintained on file within the testing laboratory.

Isolation

Rabbits were isolated and monitored for at least five days after arrival and before release to the testing facility.

Animal Identification

All rabbits were identified by cage numbers and uniquely-numbered, metal ear tags.

TEST PROCEDURES AND CONDITIONS

Test Procedure Guideline

OECD Guideline for Testing of Chemicals: Guideline 405, Dated 12 May, 1981; (Annex V, test B.5).

Dose Level

0.1 milliliter/eye

TEST PROCEDURES AND CONDITIONS, Cont.

Preparations

Both eyes of each rabbit selected for the study were tested with fluorescein dye and examined within 24 hours of administering the test material. Animals showing eye irritation, ocular defects, or pre-existing corneal injury were not used.

Identification Numbers of Animals Used

Unwashed: 947

Washed: 950

Control Substance

No control substance was used. The untreated eye of each animal served as a control for the test.

Dosing Regimen

A single dose of 0.1 milliliter of the test material was placed into the conjunctival sac of one eye of each of the two animals. One of the two treated eyes was washed with distilled water. The treated remaining eye was not irrigated.

Vehicle

No vehicle was used.

Clinical Observations

Eyes were observed immediately after instillation of the test material and 1 and 24 hours thereafter. Observations included indications of immediate sensory irritation and estimations of edema and erythema of the cornea and adnexal structures. Also evaluated were effects on the iris, the presence of corneal opacity and/or discharge from the eye. Eyes were treated with a 2% ophthalmic solution of fluorescein at 24 hours and observed for staining.

TEST PROCEDURES AND CONDITIONS, Cont.

Body Weight Determinations

Animals were not weighed as weights are not critical to this study.

Necropsy

No necropsies were conducted at the conclusion of the test.

RESULTS

Clinical Observations

Effects were graded according to OECD Guideline 405 (Annex V Test B.5).

ANIMAL NUMBER	IRRIGATED	EFFECTS (Corneal Opacity, Iris Effects, Erythema, and Chemosis)			
		1 Hour	24 Hours		
947	No	0,0,2,2	0,0,3,3		
950	Yes	0,0,2,1	0,0,2,0		

Description of Other Serious Ocular Lesions, Including Fluorescein Staining

For the unwashed eye, other lesions during the 24-hour observation period included slight erythema of the lids one hour after dosing and moderate erythema and edema of the lids at the 24-hour examination. In addition, a moderate discharge was noted at the one- and 24-hour examinations. Staining of the conjunctiva and nictitating membrane were evident for the unwashed eye when eyes were tested with fluorescein dye 24 hours after administration of the test material.

For the washed eye, other lesions included slight erythema of the lids noted at the one- and 24-hour examinations. A slight discharge was also noted at the one-hour examination. Staining of the nictitating membrane was evident 24 hours after administration of the material.

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RESULTS, Cont.

Description of Non-Ocular Effects

No non-ocular effects were observed.

Effects of Immediate Washing

Immediate irrigation of the eyes was palliative.

DATA ANALYSIS

Not applicable

DISCUSSION AND INTERPRETATION

In vitro assays (EYTEXTM Assay and NeutralRed BioAssayTM) which were conducted prior to this screening study indicated that the test material might be irritating to the eyes. However, the pH value of the test material was 6.2, a dermal application study showed no irritation, and data on other materials with similar chemical structure indicated that the test material would not be an irritant. To remove the ambiguity of these results, a screening study was conducted using two rabbits. A single dose of 0.1 milliliter of the test material was administered into the conjunctival sac of one eye of each of the two animals. One of the two treated eyes was washed with distilled water. The remaining treated eye was not irrigated.

One hour after dosing, signs of irritation in the unwashed eye were limited to moderate erythema and edema of the conjunctiva and nictitating membrane and slight erythema of the lids. A moderate discharge was also noted from this eye at the one-hour examination. However, by the 24-hour examination, the irritation response had progressed to strong erythema and strong edema of the conjunctiva and nictitating membrane and moderate erythema and moderate edema of the lids. The moderate discharge from the unwashed eye was still present at this observation period. When fluorescein dye was applied to the unwashed eye at the 24-hour examination, staining of the conjunctiva and nictitating membrane was evident.

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DISCUSSION AND INTERPRETATION, Cont.

Immediate irrigation of the eye was palliative. Signs of irritation noted in the washed eye one hour after dosing included moderate erythema of the conjunctiva, moderate erythema and slight edema of the nictitating membrane, and slight erythema of the lids. A slight discharge was also noted from the washed eye one hour after dosing. By the 24-hour examination, signs of irritation included moderate erythema of the conjunctiva and nictitating membrane and slight erythema of the lids. Staining of the nictitating membrane was evident when the washed eye was tested with fluorescein dye.

Due to the irritant effects noted in the unwashed eye during the 24 hours after instillation of the test material, the screening study was terminated and a definitive eye irritation study was not conducted as there was sufficient information available to properly classify the test material for eye irritancy.

CONCLUSION

Based on the responses observed, the test material was classified as irritating to eyes, as defined in the 12th Adaptation on the EC Classification, Packaging, and Labelling of Dangerous Substances.

DATA STORAGE

All test results presented in this report are supported by raw data which are maintained in the archives of the Corporate Health and Environment Laboratories, Eastman Kodak Company.

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SIGNATURE PAGE

Study Director	Normber 23, 1993 Date
Unit Director, Mammalian Toxicology Section	Mov 22,1993 Date
Director Corporate Health and Environment Laboratories	Nov 22, 1993 Date

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Contains No CBI

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STUDY TITLE

THANOL R-650X POLYOL (PM 17278)

ACUTE EYE IRRITATION SCREENING STUDY IN THE RABBIT

HAEL NUMBER: 93-0101 KAN: 971132 CAS REGISTRY NUMBER: 068610-97-9

FINAL REPORT

<u>AUTHOR</u>

Kenneth P. Shepard, B.S.

PERFORMING LABORATORY

Toxicological Sciences Laboratory
Corporate Health and Environment Laboratories
Eastman Kodak Company
1100 Ridgeway Avenue
B-320 Kodak Park
Rochester, New York 14652-3615
USA

LABORATORY PROJECT ID

HAEL Number: 93-0101

STUDY SPONSOR

Eastman Chemical Company Kingsport, Tennessee 37622

STUDY COMPLETION DATE

November 29, 1993

OFFICE OF POLLUTION PROVIDED TO XIO

QUALITY ASSURANCE INSPECTION STATEMENT

[21 CFR 58.35(B)(7), 40 CFR 792.35(B)(7), and 40 CFR 160.35(B)(7)]

STUDY: 93-0101-1 STUDY DIRECTOR: SHEPARD, K.P. PAGE 11/23/93

STUDY TYPE: RABBIT EYE IRRITATION

(AUDITOR, QUALITY ASSURANCE UNIT)

TO THE BEST OF MY KNOWLEDGE, THIS FINAL REPORT ACCURATELY DESCRIBES THE METHODS AND STANDARD OPERATING PROCEDURES, AND THE REPORTED RESULTS ACCURATELY REFLECT THE RAW DATA. THIS STUDY WAS INSPECTED BY 1 OR MORE PERSONS OF THE QUALITY ASSURANCE UNIT OF HAEL, EASTMAN KODAK COMPANY ROCHESTER, N.Y. AND WRITTEN STATUS REPORTS WERE SUBMITTED ON THE FOLLOWING DATES:

INSPECTION DATES	PHASE(S) INSPECTED	STATUS REPORT DATES
10/18/93	PROTOCOL APPENDIX SUBMISSION INITIALLY 2 RABBITS	
10/21/93	TEST ARTICLE DISTRIBUTION RECORDS	11/23/93
11/23/93	FINAL REPORT REVIEW	11/23/93

COMPLIANCE WITH GOOD LABORATORY PRACTICE STANDARDS

To the best of the signer's knowledge and belief, the study described by this report was conducted in compliance with the following Good Laboratory Practice Standards:

Annex 2 of the Organization for Economic Cooperation and Development Guidelines for Testing of Chemicals C(81)30 (Final) as required by Council Directive 87/18/EEC of December 18, 1986.

Kenneth P. Shepard, B.S.

Study Director

Marchan 29, 1993

Date

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ABSTRACT

THANOL R-650X POLYOL (PM 17278)

ACUTE EYE IRRITATION SCREENING STUDY IN THE RABBIT

HAEL NUMBER: 93-0101 KAN: 971132 CAS REGISTRY NUMBER: 068610-97-9

This screening study for eye irritation was initiated in lieu of a study using a complete set of animals because *in vitro* assays indicated that the test material might be an eye irritant even though prior experience with other test materials belonging to the same chemical class indicated that the test material would not be an irritant. A single dose of 0.1 milliliter of the test material was administered into the conjunctival sac of one eye of each of the two animals. One of the two treated eyes was washed with distilled water. The remaining treated eye was not irrigated.

Signs of irritation in the unwashed eye included moderate erythema and severe edema of the conjunctiva, nictitating membrane, and lids; corneal opacity to the degree that opalescent areas involved more than one-half of the cornea; and injection of the iris. A profuse discharge was also noted from the unwashed eye. When fluorescein dye was applied to the unwashed eye, staining of the conjunctiva, nictitating membrane, and cornea were evident. Immediate irrigation of the eye was palliative. Signs of irritation noted in the washed eye were limited to slight erythema of the conjunctiva, nictitating membrane, and lids and slight edema of the conjunctiva and nictitating membrane. A slight discharge was also noted from the washed eye. No staining was evident when the washed eye was tested with fluorescein dye.

Based on the responses observed, the material was classified as irritating to eyes, as defined in the 12th Adaptation on the EC Classification, Packaging, and Labelling of Dangerous Substances.

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PERFORMING LABORATORY

Toxicological Sciences Laboratory
Corporate Health and Environment Laboratories
Eastman Kodak Company
1100 Ridgeway Avenue
B-320 Kodak Park
Rochester, New York 14652-3615
USA

SPONSOR

Eastman Chemical Company Kingsport, Tennessee 37622 Sponsor's Representative: W. Mills Dyer, Jr., M.D.

STUDY DATES

Study Initiation: October 18, 1993

Experiment Initiation: October 18, 1993 Experiment Completion: October 19, 1993 Study Completion: November 29, 1993

STUDY DIRECTOR

Kenneth P. Shepard, B.S.

OTHER KEY PERSONNEL

Len Sakal, B.S., Study Technician
John W. Mosher, B.S., Principal Investigator
Milan S. Vlaovic, D.V.M., Ph.D., Laboratory Animal Medicine

PURPOSE/OBJECTIVE

The purpose of this study was to determine the potential of the test compound to cause primary ocular irritation.

TEST SUBSTANCE

Test Material Name: THANOL R-650X Polyol

PM: 17278

CAS Registry Number: 068610-97-9 HAEL Laboratory Number: 93-0101

KAN: 971132 CIN: Not available

SRID or Lot I.D. Number: X22872-026C

Physical State and Appearance: Yellow-red viscous liquid

Received at Performing Laboratory: August 9, 1993

Composition: Refer to composition information included in the notification when applicable.

TEST SYSTEM

Species: Rabbit

Strain: Hra:(NZW)SPF

Source: Hazleton Research Animals, Denver, PA, USA

No. of Animals: 2; 1 Washed/1 Unwashed

Sex: Not Determined

Body Weight Range at Dosing: Not Determined Age: Young Adults (At least three months old)

HUSBANDRY AND ENVIRONMENTAL CONDITIONS

Housing

All animals were individually housed in suspended, stainless-steel, mesh cages.

HUSBANDRY AND ENVIRONMENTAL CONDITIONS, Cont.

Environmental Conditions

A photoperiod of 12 hours light from 6 a.m. to 6 p.m.was maintained. Room temperature was maintained at 65-67°F. Relative humidity was maintained at 63-64%.

Diet and Water

Agway® Prolab™ High Fiber Rabbit Diet certified pellets and water (Monroe County (NY) Water Authority) were available ad libitum. No known contaminants which would interfere with the outcome of the study were expected to be present in feed or water from these sources. Analyses of feed and quarterly analyses of water are maintained on file within the testing laboratory.

Isolation

Rabbits were isolated and monitored for at least five days after arrival and before release to the testing facility.

Animal Identification

All rabbits were identified by cage numbers and uniquely-numbered, metal ear tags.

TEST PROCEDURES AND CONDITIONS

Test Procedure Guideline

OECD Guideline for Testing of Chemicals: Guideline 405, Dated 12 May, 1981; (Annex V, test B.5).

Dose Level

0.1 milliliter/eye

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TEST PROCEDURES AND CONDITIONS, Cont.

Preparations

Both eyes of each rabbit selected for the study were tested with fluorescein dye and examined within 24 hours of administering the test material. Animals showing eye irritation, ocular defects, or pre-existing corneal injury were not used.

Identification Numbers of Animals Used

Unwashed: 953

Washed: 956

Control Substance

No control substance was used. The untreated eye of each animal served as a control for the test.

Dosing Regimen

A single dose of 0.1 milliliter of the test material was placed into the conjunctival sac of one eye of each of the two animals. One of the two treated eyes was washed with distilled water. The treated remaining eye was not irrigated.

Vehicle

No vehicle was used.

Clinical Observations

Eyes were observed immediately after instillation of the test material and 1 and 24 hours thereafter. Observations included indications of immediate sensory irritation and estimations of edema and erythema of the cornea and adnexal structures. Also evaluated were effects on the iris, the presence of corneal opacity and/or discharge from the eye. Eyes were treated with a 2% ophthalmic solution of fluorescein at 24 hours and observed for staining.

TEST PROCEDURES AND CONDITIONS, Cont.

Body Weight Determinations

Animals were not weighed as weights are not critical to this study.

Necropsy

No necropsies were conducted at the conclusion of the test.

RESULTS

Clinical Observations

Effects were graded according to OECD Guideline 405 (Annex V Test B.5).

ANIMAL		EFFECTS (Corneal Opacity, Iris Effects, Erythema, and Chemosis)				
NUMBER	IRRIGATED	1 Hour	24 Hours			
953	No	0,0,2,3	3,1,2,4			
956	Yes	0,0,1,1	0,0,1,0			

Description of Other Serious Ocular Lesions, Including Fluorescein Staining

For the unwashed eye, other lesions during the 24-hour observation period included moderate erythema and slight edema of the lids one hour after dosing and moderate erythema and severe edema of the lids at the 24-hour examination. A profuse discharge was also noted from the unwashed eye at the one-hour and 24-hour examinations. Staining of the conjunctiva, nictitating membrane, and cornea were evident for the unwashed eye when eyes were tested with fluorescein dye 24 hours after administration of the test material.

For the washed eye, other lesions were limited to slight erythema of the lids one hour after dosing. A slight discharge was also noted at the one-hour examination. No staining was evident 24 hours after administration of the material.

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RESULTS, Cont.

Description of Non-Ocular Effects

No non-ocular effects were observed.

Effects of Immediate Washing

Immediate irrigation of the eyes was palliative.

DATA ANALYSIS

Not applicable

DISCUSSION AND INTERPRETATION

In vitro assays (EYTEXTM Assay and NeutralRed BioAssayTM) which were conducted prior to this screening study indicated that the test material might be irritating to the eyes. However, the pH value of the test material was 6.7, a dermal application study showed no irritation, and data on other materials with similar chemical structure indicated that the test material would not be an irritant. To remove the ambiguity of these results, a screening study was conducted using two rabbits. A single dose of 0.1 milliliter of the test material was administered into the conjunctival sac of one eye of each of the two animals. One of the two treated eyes was washed with distilled water. The remaining treated eye was not irrigated.

One hour after dosing, signs of irritation in the unwashed eye were limited to moderate erythema and strong edema of the conjunctiva and nictitating membrane and moderate erythema and slight edema of the lids. A profuse discharge was also noted from this eye at the one-hour examination. However, by the 24-hour examination, the irritation response had progressed to moderate erythema and severe edema of the conjunctiva, nictitating membrane, and lids; corneal opacity to the degree that opalescent areas involved more than one-half of the cornea; and injection of the iris. The profuse discharge was still present 24 hours after dosing. When fluorescein dye was applied to the unwashed eye at the 24-hour examination, staining of the conjunctiva, nictitating membrane, and cornea were evident.

DISCUSSION AND INTERPRETATION, Cont.

Immediate irrigation of the eye was palliative. Signs of irritation noted in the washed eye one hour after dosing included slight erythema of the conjunctiva, nictitating membrane, and lids; and slight edema of the conjunctiva and nictitating membrane. A slight discharge was also noted from the washed eye one hour after dosing. By the 24-hour examination, signs of irritation were limited to slight erythema of the conjunctiva and nictitating membrane. No staining was evident when the washed eye was tested with fluorescein dye.

Due to the irritant effects noted in the unwashed eye during the 24 hours after instillation of the test material, the screening study was terminated and a definitive eye irritation study was not conducted as there was sufficient information available to properly classify the test material for eye irritancy.

CONCLUSION

Based on the responses observed, the test material was classified as irritating to eyes, as defined in the 12th Adaptation on the EC Classification, Packaging, and Labelling of Dangerous Substances.

DATA STORAGE

All test results presented in this report are supported by raw data which are maintained in the archives of the Corporate Health and Environment Laboratories, Eastman Kodak Company.

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SIGNATURE PAGE

Study Director	November 29, 1993 Date
Unit Director, Mammalian Toxicology Section	Nov 24,1493 Date
Director Corporate Health and Environment Laboratories	Nc 1 29, 1993 Date

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000000248/F/USA

Approval Date: 12/03/1993 Print Date: 12/03/1993

Page 1

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1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: "THANOL" R-650X Polyol

Product Identification Number(s): SPC 26528

Manufacturer/Supplier: Eastman Chemical Company, Kingsport, Tennessee 37662

MSDS Prepared by: Product Safety Department, Eastman Chemical Company,

Kingsport, TN 37662

For Emergency Health, Safety & Environmental Information, Call: 800-EASTMAN

For Emergency Transportation Information, Call CHEMTREC: 800-424-9300 or call: 800-EASTMAN

For Other Information, Call your Eastman representative or the Eastman operator 615-229-2000 (USA)

Chemical Name: formaldehyde, polymer with nonylphenol, reaction products with diethanolamine and propylene oxide

Synonym(s): PM 17278; KAN 971132

Molecular Formula: not available

Molecular Weight: not available

Product Use: chemical intermediate

2. COMPOSITION/INFORMATION ON INGREDIENTS

Weight % - Component - (CAS Registry No.)

formaldehyde, polymer with nonylphenol, reaction products with diethanolamine and propylene oxide (068610-97-9)

HAZARDS IDENTIFICATION

WARNING!

CAUSES EYE IRRITATION

HMIS Hazard Ratings: Health - 2, Flammability - 1, Chemical Reactivity - 0

NFPA Hazard Ratings: Health - 2, Flammability - 1, Chemical Reactivity - 0

NOTE: HMIS and NFPA ratings involve data and interpretations that may vary from company to company. They are intended only for rapid, general identification of

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000000248/F/USA

Approval Date: 12/03/1993 Print Date: 12/03/1993

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Exposure Limits:

ACGIH Threshold Limit Value (TLV): not established

OSHA (USA) Permissible Exposure Limit (PEL, 1989 Table Z-1-A values or section-specific standards): not established

| Ventilation: Good general ventilation (typically 10 air changes per hour) should | be used. Ventilation rates should be matched to conditions. Supplementary local | exhaust ventilation, closed systems, or respiratory protection may be needed in | special circumstances such as poorly ventilated spaces, evaporation from large | surfaces, spraying, heating, etc.

Respiratory Protection: If engineering controls do not maintain airborne concentrations to an acceptable level, an approved respirator must be worn. Respirator type: mist. If respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134.

Eye Protection: Wear safety glasses with side shields (or goggles).

Skin Protection: It is a good industrial hygiene practice to minimize skin contact.

Recommended Decontamination Facilities: eye bath, washing facilities

9. PHYSICAL AND CHEMICAL PROPERTIES

- Physical Form: viscous liquid
- Color: yellow
- Odor: mild
- Odor Threshold: not available
- Specific Gravity at 4°C (39°F) (water = 1): 1.06
- Vapor Pressure: negligible
- Vapor Density (Air = 1): not available
- Evaporation Rate: negligible
- Boiling Point: not available
- Melting Point: not available
- Viscosity at 25°C (77°F): 30000 mPa.s or cP
- Solubility in Water: slight
- | pH: 9.7 (as is)
- Octanol/Water Partition Coefficient: not available
- Flash Point (Pensky-Martens closed cup): 152°C (305°F)
- | Lower Explosive Limit: not available
- Upper Explosive Limit: not available
- | Autoignition Temperature: not available
- Sensitivity to Mechanical Impact: not available
- | Sensitivity to Static Discharge: not available

| 10. STABILITY AND REACTIVITY

MATERIAL SAFETY DATA SHEET

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.....

- | Sea International Maritime Dangerous Goods (IMDG)
- | IMDG Status: not regulated

15. REGULATORY INFORMATION

- | This document has been prepared in accordance with the MSDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.
- | OSHA hazardous chemical(s): formaldehyde, polymer with nonylphenol, reaction products with diethanolamine and propylene oxide
 - Material(s) known to the State of California to cause cancer: none
 - Material(s) known to the State of California to cause adverse reproductive effects: none
 - Massachusetts Substance List: none
- New Jersey Workplace Hazardous Substance List: none
- | Pennsylvania Hazardous Substance List: none
- This document has been prepared in accordance with the MSDS requirements of the WHMIS Controlled Products Regulation.
- | WHMIS (Canada) Ingredient Disclosure List: none
- | WHMIS (Canada) Status: controlled
- WHMIS (Canada) controlled material(s): formaldehyde, polymer with nonylphenol, reaction products with diethanolamine and propylene oxide
- WHMIS (Canada) Hazard Classification: D/2/B
- | Carcinogenicity Classification (components present at 0.1% or more):
 - International Agency for Research on Cancer (IARC): not listed
 - American Conference of Governmental Industrial Hygienists (ACGIH): not listed
 - National Toxicology Program (NTP): not listed
 - Occupational Safety and Health Administration (OSHA): not listed
- | Chemical(s) subject to the reporting requirements of Section 313 or Title III of the Superfund Amendments and Reauthorization Act (SARA) of 1986 and 40 CFR Part 372: none
- SARA (U.S.A.) Sections 311 and 312 hazard classification(s): immediate (acute) health hazard
- US Toxic Substances Control Act (TSCA): This product is listed on the TSCA inventory or otherwise complies with TSCA premanufacture notification requirements.
- Canadian Environmental Protection Act (CEPA) and Domestic Substances List (DSL): This product is listed on the DSL or otherwise complies with CEPA new substance notification requirements.
- | European Inventory of Existing Commercial Chemical Substances (EINECS): This product is listed on EINECS or has been approved in the European Community by new substance notification.

EASTMAN Contains No CBI

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Page 1

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: "THANOL" R-350X Polyo1

Product Identification Number(s): SPC 26524

Manufacturer/Supplier: Eastman Chemical Company, Kingsport, Tennessee 37662

MSDS Prepared by: Product Safety Department, Eastman Chemical Company, Kingsport, TN 37662

For Emergency Health, Safety & Environmental Information, Call: 800-EASTMAN

For Emergency Transportation Information, Call CHEMTREC: 800-424-9300 or call: 800-EASTMAN

For Other Information, Call your Eastman representative or the Eastman operator 615-229-2000 (USA)

Chemical Name: alpha-hydro-omega-hydroxy-poly(oxy(methyl-1,2-ethanediyl) ether with bis (((2-hydroxyethyl)amino)methyl)phenol (3:1)

Synonym(s): KAN 971130; PM 17276-00; polymer of propylene oxide and bis(((2-hydroxyethyl)amino)methyl)phenol

Molecular Formula: not available

Molecular Weight: not available

Product Use: chemical intermediate

2. COMPOSITION/INFORMATION ON INGREDIENTS

Weight % - Component - (CAS Registry No.)

polymer of propylene oxide and bis(((2-hydroxyethyl)amino)methyl)phenol (068909-26-2)

3. HAZARDS IDENTIFICATION

WARNING!

CAUSES EYE IRRITATION

HMIS Hazard Ratings: Health - 2, Flammability - 1, Chemical Reactivity - 0

| NFPA Hazard Ratings: Health - 2, Flammability - 1, Chemical Reactivity - 0

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limits:

ACGIH Threshold Limit Value (TLV): not established

OSHA (USA) Permissible Exposure Limit (PEL, 1989 Table Z-1-A values or section-specific standards): not established

Ventilation: Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. Supplementary local exhaust ventilation, closed systems, or respiratory protection may be needed in special circumstances such as poorly ventilated spaces, evaporation from large surfaces, spraying, heating, etc.

Respiratory Protection: If engineering controls do not maintain airborne concentrations to an acceptable level, an approved respirator must be worn. Respirator type: mist. If respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134.

Eye Protection: Wear safety glasses with side shields (or goggles).

Skin Protection: It is a good industrial hygiene practice to minimize skin contact.

Recommended Decontamination Facilities: eye bath, washing facilities

9. PHYSICAL AND CHEMICAL PROPERTIES

- Physical Form: liquid
- Color: yellow
- Odor: mild
- Odor Threshold: not available
- Specific Gravity at 4°C (39°F) (water = 1): 1.12
- Vapor Pressure: negligible
- Vapor Density (Air = 1): not available
- Evaporation Rate: negligible
- | Boiling Point: not available
- Melting Point: not available
- Viscosity at 25°C (77°F): 15000 mPa.s or cP
- | Solubility in Water: appreciable
- pH: 6.2 (as is)
- Octanol/Water Partition Coefficient: not available
- Flash Point (Pensky-Martens closed cup): >149°C (>300°F)
- | Lower Explosive Limit: not available
- Upper Explosive Limit: not available
- | Autoignition Temperature: not available
- | Sensitivity to Mechanical Impact: not available
- | Sensitivity to Static Discharge: not available

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Page 5

- Air International Civil Aviation Organization (ICAO)
- ICAO Status: not regulated
- Sea International Maritime Dangerous Goods (IMDG)
- | IMDG Status: not regulated

15. REGULATORY INFORMATION

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- Material(s) known to the State of California to cause cancer: none
- Material(s) known to the State of California to cause adverse reproductive effects: none
- Massachusetts Substance List: none
- New Jersey Workplace Hazardous Substance List: none
- | Pennsylvania Hazardous Substance List: none
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 - National Toxicology Program (NTP): not listed
 - Occupational Safety and Health Administration (OSHA): not listed
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- Canadian Environmental Protection Act (CEPA) and Domestic Substances List (DSL): This product is listed on the DSL or otherwise complies with CEPA new substance notification requirements.
- | European Inventory of Existing Commercial Chemical Substances (EINECS): Any



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

R. Hays Bell, Ph.D. Vice President, Corporate Health, Safety, and Environment Eastman Kodak Company 343 State Street Rochester, New York 14650

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

APR 1 9 1994

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite this number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan

Risk Analysis Branch

Enclosure

12787 A

Printed on Recycled Paper

Triage of 8(e) Submissions

	ounce - AUG					
Date sent to triag	e; <u>MAY 1</u>	8 1354		ION-CAP)	CAP	
Submission numb	er <u>1278</u>	67 A	Т	SCA Inventory:	N	D
Study type (circle	appropriate):					
Group 1 - Dick Cl	ements (1 copy tot	ai)				
ECO	AQUATO					
Group 2 - Erne Fa	alke (1 copy total)					
(ATOX)	SBTOX	SEN	w/NEUR			
Group 3 - Elizabet	th Margosches (1 c	copy each)				
этох	CTOX/ONCO	стох	RTOX	GTOX		
NEUR	EPI	IMMUNO	СУТО			
Other (FATE, EXPO), MET, etc.):					
Notes:						
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SUB. DATE: 1214 93 OTS DATE: 1216			INFORMATION REQUESTED FLWP DATE: 0501 NO INFO REQUESTED) 0502 INFO REQUESTED (TECH) 0503 INFO REQUESTED (VOL ACTIONS) 0504 INFO REQUESTED (REPORTING RATIONALE) DISPOSITION: 0639 REFER TO CHEMICAL SCREENING 0678 CAP NOTICE			VAFENTARY ACTIONS 0401 NO ACTION REPORTED 0402 STUDIES PLANNEDAINDERWAY 0403 NOTIFICATION OF WORKERATHERS 0404 LABELMSDS CHANGES 0405 PROCESSMANDLING CHANGES 0406 APPAISE DISCONTINUED 0407 PRODUCTION DISCONTINUED 0408 CONFIDENTIAL		
Thand R-350x Thand R-650x	Polyol			CASE 68909-1				
INFORMATION TYPE:	PFC	INFOR	MATION TYPE:	PFC	INFORI	MATION TYPE:	<u> P F C</u>	
0201 ONCO (HUMAN) 0202 ONCO (ANIMAL) 0203 CELL TRANS (IN VITRO) 0204 MUTA (IN VITRO) 0205 MUTA (IN VIVO) 0206 REPRO/TERATO (HUMAN) 0207 REPRO/TERATO (ANIMAL) 0208 NEURO (HUMAN) 0209 NEURO (ANIMAL) 0210 ACUTE TOX. (HUMAN) 0211 CHR. TOX. (HUMAN) 0212 ACUTE TOX. (ANIMAL) 0213 SUB ACUTE TOX (ANIMAL) 0214 SUB CHRONIC TOX (ANIMAL) 0215 CHRONIC TOX (ANIMAL)	01 02 04 01 02 04	0216 0217 0218 0219 0220 0221 0222 0223 0225 0226 0227 0228 0239 0240	EPI/CLIN HUMAN EXPOS (PROD CONT/ HUMAN EXPOS (ACCIDENTAL HUMAN EXPOS (MONITORING ECO/AQUA TOX ENV. OCCC/REL/FATE EMER INCI OF ENV CONTAM RESPONSE REQEST DELAY PROD/COMP/CHEM ID REPORTING RATIONALE CONFIDENTIAL ALLERG (HUMAN) ALLERG (ANIMAL) METAB/PHARMACO (HUMAN)	0) 01 02 04 0) 02 04 01 02 04	0241 0242 0243 0244 0245 0246 0247 0248 0251 0299	IMMUNO (ANIMAL) IMMUNO (HUMAN) CHEM/PHYS PROP CLASTO (IN VITRO) CLASTO (ANIMAL) CLASTO (HUMAN) DNA DAM/REPAIR PROD/USE/PROC MSDS OTHER	01 02 04 01 02 04	
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DETERMINE COMMENTS:	REFER:	· - ,	HIGH	AR IRRITAT				

8(e)-12787A

R-350X MEDIUM

01

Ocular irritation in the rabbit is medium concern because the test material produced strong erythema and edema of conjunctivae, nictitating membranes and moderate erythema edema of the lids. The study was terminated at 24 hours.

R-650X MEDIUM

02

Ocular irritation in the rabbit is medium concern because the test material produced moderate erythema and severe edema of the conjunctivae, nictitating membrane and lids, corneal opacity, and injection of the iris. The test was terminated at 24 hours.